MAR 8 2013

9.0 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024 Japan
OFFICIAL CORRESPONDENT	Yoshi Terai President, CEO Asahi Intecc USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252 FAX (949) 756-8165 e-mail: yoshi.terai@asahi-intecc.com
TRADE NAME:	ASAHI SION J PTCA Guide Wire
COMMON NAME:	Guide Wire
CLASSIFICATION NAME:	Wire, Guide, Catheter
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
PRODUCT CODE	DQX - Catheter Guide Wire
PREDICATE DEVICE:	1. Asahi Intecc - ASAHI SION PTCA Guide Wire - 510(k) K100578

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ASAHI SION J PTCA Guide Wire is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180 cm and 300 cm lengths. The guide wire is constructed from a stainless steel core wire with platinum-nickel and stainless steel coils. The coil assembly consists of an inner coil and an outer coil, and there is a safety wire for which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility, and is available as a pre shaped "J ". A hydrophilic coating is applied to the distal portion of the guide wire. The proximal section of the guide wire is coated with PTFE. The extension wire is connected to the end of the guide wire outside the body for 180 cm wire.

INDICATION FOR USE:

ASAHI PTCA GUIDE WIRES are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA GUIDE WIRES are not to be used in the cerebral blood vessels.

TECHNICAL CHARACTERISTICS:

Comparisons of the ASAHI SION J PTCA Guide Wire and predicate devices show that the technological characteristics, the materials and the manufacturing processes used in the SION J device are the same as those used in the previously 510(k) cleared Asahi predicate devices. This submission represents a change to the tip configuration from a straight Tip design to a pre-shaped J design.

PERFORMANCE DATA:

Enclosed within this submission is performance data that demonstrates that the ASAHI SION J PTCA Guide Wire meets all predetermined performance criteria and performs as intended. All components that come in direct contact with the patient have a long history of use in medical devices and are proven to be biocompatible for use in the vasculature. Furthermore, this submission contains reference to predicate ASAHI devices that use the same materials as used in the subject device.

In vitro bench testing, including tensile strength, torque strength, torqueability, tip flexibility, coating adherence and catheter compatibility as listed below were conducted on the ASAHI SION J PTCA Guide Wire. And the particulate evaluation was leveraged from the predicate device with identical product constructions, materials and manufacturing process except a "J" tip shape of the Guide Wire.

Performance test/evaluation summary:
Device performance:
Tensile Strength
Turns to Failure (Torque Strength)
Torqueability (Torque Response)
Tip Flexibility
Coating Adhesion
Slipping Ability of Guide Wire with PTCA Balloon Catheter
Particulate testing

The biocompatibility has been established by the successful use of the same materials and manufacturing process in currently 510(k) approved Asahi Guide Wire products. The biocompatibility testing as listed below was leveraged from the predicate devices with identical materials and manufacturing process.

Biocompatibility/evaluation:
Systemic Toxicity Study
In Vitro Hemolysis Study
Intracutaneous Study
Cytotoxicity Study
Sensitization Study
Pyrogen Study

Plasma Recalcification Time Coagulation Study
In Vivo Thromboresistance Study
C3a Complement Activation Study
SC5b-9 Complement Activation Study

SUMMARY/CONCLUSION:

The ASAHI SION J PTCA Guide Wire characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Asahi Intecc USA, Inc.
c/o Mr. Yoshi Terai
2500 Red Hill Avenue, Suite 210
Santa Ana, CA 92705

Re: K122469
Trade/Device Name: ASAHI SION J PTCA Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 17, 2013
Received: February 8, 2013

Dear Mr. Terai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122469

Device Name: ASAHI SION J PTCA Guide Wire

Indications for Use:

ASAHI PTCA GUIDE WIRES are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA GUIDE WIRES are not to be used in the cerebral blood vessels.

Prescription Use X AND/OR Over-The-Counter Use ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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